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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,989	05/24/2006	Rami Evron	PHUS030466US2	1420

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EXAMINER	
SANEI, MONA M	

ART UNIT	PAPER NUMBER
2882	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,989	EVRON, RAMI	
	Examiner	Art Unit	
	MONA M. SANEI	2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 15-19* is/are rejected.

7)☒ Claim(s) *12-14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 May 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

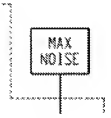
Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/24/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. Figure 1 is objected to because the box labeled "Max Noise" is missing a reference number (see cut-out of figure 1 below).



2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

- 26 (see para 0018 of PG-Pub)
- 28 (see para 0018 of PG-Pub)

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities (see PG-Pub):

- In para 0021, line 2, "device 10" should read - -device 20- -.
- In para 0021, line 5, "detector 44" should read - -detector 14- -.

Appropriate correction is required.

Claim Objections

4. Claims 1-18 are objected to because of the following informalities:

- In claim 1, line 4, "and," should read - -and- -.
- In claim 2, line 1, "wherein, the" should read - -wherein the- -.
- In claim 2, line 4, "patent" should read - -patient- -.
- In claim 4, line 7, "and," should read - -and- -.
- In claim 7, line 7, "and," should read - -and- -.
- In claim 8, line 3, "examined;" should read - -examined; and- -.
- In claim 8, line 5, "doses" should read - -dose- -.
- In claim 11, line 5, "and," should read - -and- -.
- In claim 17, line 3, "examination;" should read - -examination; and- -.
- Claims 3, 5, 6, 9, 10, 12-16, and 18 are objected to by virtue of their dependencies.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2, 4-7, and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 2, lines 1-2, "the dose selection processor" lacks proper antecedent basis.
- In claim 4, lines 1-2, "the dose selection processor" lacks proper antecedent basis.
- In claim 4, line 3, "the dose selection processor" lacks proper antecedent basis.
- In claim 5, line 4, "the target required dose" lacks proper antecedent basis.
- In claim 6, lines 1-2, "the dose selection processor" lacks proper antecedent basis.
- In claim 6, line 2, "the tube controller" lacks proper antecedent basis.
- In claim 7, lines 1-2, "the x-ray scanner" lacks proper antecedent basis.
- In claim 17, line 3, "the diagnostic examination" lacks proper antecedent basis.
- In claim 19, line 1, "the target noise level" lacks proper antecedent basis.
- In claim 19, line 2, "the noise level" lacks proper antecedent basis.
- Claims 5, 18, and 19 are rejected by virtue of their dependencies.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kleinman (US 4597094).

- Regarding claim 1, Kleinman teaches a system comprising an x-ray tube (10) for irradiating a patient (12) with an x-ray beam (10b), a dose controller for controlling milliamperes (mAs) of an x-ray tube current to control radiation dose, and a dose processor for calculating a target maximum patient dose in accordance with physical parameters of the patient to be irradiated (col. 2, lines 49-66; col. 4, lines 19-45; fig. 1).
- Regarding claim 8, Kleinman a method including selecting a target required radiation dose of an x-ray tube in accordance with physical parameters of a patient to be examined and performing an x-ray diagnostic examination of the patient with an x-ray beam with the selected radiation doses (col. 2, lines 49-66; col. 4, lines 19-45; fig. 1).

7. Claims 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Mahnken et al. (Detection of Colonary Calcifications: Feasibility of Dose Reduction with a Body Weight-Adapted Examination Protocol; August 2003; AJR; 181:533-538).

- Regarding claims 8, Mahnken et al. teaches a method including selecting a target required radiation dose of an x-ray tube in accordance with physical parameters of a patient to be examined and performing an x-ray diagnostic examination of the patient with an x-ray beam with the selected radiation doses (pg. 533, see sections labeled, "objective" and "results"; pg. 533, col. 2, last para; pg. 534, col. 1, para 1; pg. 534, col. 3, last para; figs. 2 and 4).
- Regarding claim 10, Mahnken et al. teaches that the patient physical parameters include a weight and height of the examined patient (pg. 533, see sections labeled, "objective" and "results"; pg. 533, col. 2, last para; pg. 534, col. 1, para 1; pg. 534, col. 3, last para; figs. 2 and 4; it is noted that BMI=weight/height^2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-4, 6, 9, 11, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mahnken et al. (Detection of Colonary Calcifications: Feasibility of Dose Reduction with a Body Weight-Adapted Examination Protocol; August 2003; AJR; 181:533-538) in view of Born et al. (US 5349625).

- Regarding claims 1, 3, and 15, Mahnken et al. teaches calculating a target maximum patient dose in accordance with physical parameters of a patient to be irradiated and modulating milliamperes of an x-ray tube current of an x-ray tube to modulate radiation dose, wherein the patient parameters are the patient's height, weight, and/or a patient body mass index (pg. 533, see sections labeled, "objective" and "results"; pg. 533, col. 2, last para; pg. 534, col. 1, para 1; pg. 534, col. 3, last para; figs. 2 and 4; it is noted that BMI=weight/height^2).

However, Mahnken et al. fails to teach a dose controller for controlling the radiation dose, a dose processor for calculating the patient dose in accordance with the physical parameters of the patient, and a user input means for inputting the patient's physical parameters.

Born et al. fails to teach a dose controller for controlling a radiation dose, a dose processor for calculating a patient dose in accordance with physical parameters of the patient, and a user input means for inputting the patient's physical parameters (col. 2, line 64-col. 3, line 14; col 5, lines 7-55).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system of Mahnken et al. as suggested by Born et al. since one would have been motivated to make such a modification to providing a more efficient system that is less time consuming and more accurate.

- Regarding claims 6, 9, and 16, Mahnken et al. as modified teaches a system as recited above.

However, Mahnken et al. fails to teach that the body mass index is squared.

At the time the invention was made, it would have been an obvious matter of design choice to one having ordinary skill in the art to square the body mass index as applicant has not disclosed that squaring the body mass index provides an advantage, is used for a particular purpose, or solves any stated or long standing problem in the art. One of ordinary skill in the art, furthermore, would have expected Mahnken et al.'s system and method and applicant's system and method to perform equally well with either the body mass index as taught by Mahnken et al. or the square of the body mass index as recited in claims 6, 9, and 16 because either physical parameter would function in providing a body-adapted tube current time setting means for reducing radiation dose to the patient.

Therefore, absent any showing of criticality, it would have been obvious to one having ordinary skill in the art to modify the system and method of Mahnken et al. such that the body mass index is squared as such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Mahnken et al.

- Regarding claims 2, 4, and 11, Mahnken et al. as modified above teaches teaches squaring the patient's height, dividing the patient's weight by the patient's height squared to

generate a body mass index, squaring the body mass index. Examiner takes the position that Mahnken et al. as modified above necessarily teaches multiplying the body mass index squared by a constant to calculate the tube current for the x-ray tube (this would be a necessary step as the units of body mass index squared (kg^2/h^4) would have to somehow be converted to the units of current (mAs) in order to perform the function.

9. Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mahnken et al. (Detection of Colonary Calcifications: Feasibility of Dose Reduction with a Body Weight-Adapted Examination Protocol; August 2003; AJR; 181:533-538) and Born et al. (US 5349625) as applied to claims 6 and 16 above, and further in view of Hu et al. (US 6233304).

- Regarding claims 7 and 17, Mahnken et al. as modified above suggests a system and method as recited above. Mahnken et al. further teaches applying the body weight-adapted tube current time settings to reduce the radiation dose on the coronary calcium score (pg. 533, see section labeled "objective").

However, Mahnken et al. as modified above fails to teach a reconstruction processor for reconstructing examination data from the x-ray scanner into an image representation, a thresholding means for thresholding the image representation for calcium to generate a calcium enhanced image representation, a means for storing the calcium enhanced image representation, and, a means for displaying the calcium enhanced image representation.

Hu et al. teaches a reconstruction processor (34) for reconstructing examination data from an x-ray scanner (10) into an image representation, a thresholding means (col. 3, line 54-col. 4, line 19) for thresholding the image representation for calcium to generate a calcium enhanced

image representation, a means for storing (38) the calcium enhanced image representation, and, a means for displaying (42) the calcium enhanced image representation.

It would have been obvious to one having ordinary skill in the art at the time of the invention to further modify the system and method of Mahnken et al. as suggested by Hu et al. since one would have been motivated to make such a modification to generate a stable and consistent calcification score using image data from a the components of a CT imaging system (col. 2, lines 4-8) as implied by Hu et al.

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mahnken et al. (Detection of Colonary Calcifications: Feasibility of Dose Reduction with a Body Weight-Adapted Examination Protocol; August 2003; AJR; 181:533-538), Born et al. (US 5349625), and Hu et al. (US 6233304) as applied to claim 17 above, and further in view of Arnold et al. (US 4922915).

- Regarding claim 18, Mahnken et al. as modified above suggests a system as recited above.

However, Mahnken et al. as modified above fails to teach comparing the calcium-enhanced image representation with prior calcium-enhanced image representations of the same patient.

Arnold et al. teaches a CT imaging system including comparing an image representation with prior image representations of the same patient (col. 1, lines 43-62; col. 31, lines 27-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to further modify the system of Mahnken et al. as suggested by Arnold et al. since one

would have been motivated to make such a modification to more conveniently track changes in the calcium scoring of the patient over time (col. 31, lines 27-40) as implied by Arnold et al.

Allowable Subject Matter

11. Claims 5 and 19 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

- Regarding claim 5, the prior art fails to teach or fairly suggest an x-ray diagnostic imaging device including a target required noise memory for storing a target required noise level and a means for converting the target required dose into the constant which the multiplying means multiplies by the body mass index squared, in combination with all the other limitations of the claim.
- Regarding claim 12, the prior art fails to teach or fairly suggest a method of diagnostic imaging wherein the constant is selected in accordance with a target required noise level, in combination with all the other limitations of the claim.
- Regarding claim 19, the prior art fails to teach or fairly suggest an x-ray diagnostic imaging device wherein the target noise level of the present calcium-enhanced image representation is the same as the noise level of the prior calcium-enhanced image representations.
- Claims 13 and 14 contain allowable subject matter by virtue of their dependencies.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Klingenbeck-Regn et al. (US 7116756) teaches an x-ray diagnostic apparatus with a body mass index calculator for controlling x-ray emissions (col. 2, lines 26-64; see figures).
- Jianying (US 7636422) teaches an x-ray tube current determining method, wherein the tube current is determined based on an index related to image's noise and a BMI of a subject (col. 1, line 65-col. 2, line 3; see figures).
- Toth (US 2003/0097062) teaches a system and method of medical imaging having default noise index override capacity (see abstract).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONA M. SANEI whose telephone number is (571)272-8657. The examiner can normally be reached on M-F 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward J. Glick can be reached on (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mona M Sanei/
Examiner, Art Unit 2882

/Hoon Song/
Primary Examiner, Art Unit 2882